

## ANNEX

| Identi-<br>fication<br>number<br>of the<br>additive                   | Name of the<br>additive                                      | Composition, chemical formula,<br>description, analytical method  | Species<br>or<br>category<br>of<br>animal | Maximum<br>age | Minimum<br>content       | Maximum<br>content | Other provisions  | End of<br>period of<br>authorisa-<br>tion   |
|---|--|---|---|----------------|--------------------------|--------------------|---|---|
|   |  |   |   |                | CFU/kg of fresh material |                    |   |   |
| Category: technological additives. Functional group: silage additives |  |   |   |                |                          |                    |   |   |
| 1k21702   | <i>Lacticaseibacillus<br/>huelsenbergensis</i><br>DSM 115424 | <b>Additive composition</b><br>Preparation of <i>Lacticaseibacillus<br/>huelsenbergensis</i> DSM 115424,<br>containing a minimum of $4 \times 10^{11}$ CFU/g<br>additive.<br><br>Solid form<br><br>-----<br><b>Characterisation of the active<br/>substance</b><br>Viable cells of <i>Lacticaseibacillus<br/>huelsenbergensis</i> DSM 115424<br><br>-----<br><b>Analytical method<sup>1</sup></b><br>Identification of <i>Lacticaseibacillus<br/>huelsenbergensis</i> DSM 115424 in the<br>feed additive:<br>– Pulsed Field Gel Electrophoresis<br>(PFGE) - CEN/TS 17697 or DNA<br>sequencing methods.<br><br>Enumeration of <i>Lacticaseibacillus<br/>huelsenbergensis</i> DSM 115424 in the<br>feed additive: | All<br>animal<br>species                  | -              | -                        | -                  | <ol style="list-style-type: none"><li>1. In the directions for use of the<br/>additive and premixtures, the<br/>storage conditions shall be<br/>indicated.</li><li>2. Minimum dose of the additive,<br/>when it is not used in<br/>combination with other micro-<br/>organisms as silage additives:<br/>1x10<sup>8</sup> CFU/kg fresh plant<br/>material.</li><li>3. If used as a cryoprotectant,<br/>polyethylene glycol (PEG<br/>4000) shall be used up to a<br/>maximum concentration of<br/>0,025 mg/kg silage.</li><li>4. Cryoprotectants used in the<br/>preparation of<br/><i>Lacticaseibacillus<br/>huelsenbergensis</i> DSM 115424<br/>may include inter alia:<br/>- sodium citrate,</li></ol> | [10 years<br>from the date<br>of entry into<br>force of this<br>Regulation.<br>To be<br>completed by<br>the OP] |

<sup>1</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

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|---|-------------------------|--|---|----------------|--------------------------|--------------------|---|---|
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|   |                         | – Spread plate (or pour plate) method on<br>MRS agar (EN 15787)  |   |                |                          |                    | <div>- mannitol,<br/>- sodium glutamate<br/>monohydrate.</div> <div>5. For users of the additive and<br/>premixtures, feed business<br/>operators shall establish<br/>operational procedures and<br/>organisational measures to<br/>address potential risks resulting<br/>from their use. Where those<br/>risks cannot be eliminated by<br/>such procedures and measures,<br/>the additive and premixtures<br/>shall be used with personal skin<br/>and breathing protective<br/>equipment.</div> |   |